

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**BECON MEDICAL, LTD. and
HENRY STEPHENSON BYRD, M.D.,
Plaintiff,**

CIVIL ACTION

v.

NO. 18-4169

**SCOTT P. BARTLETT, M.D., and
TALEXMEDICAL, LLC,
Defendants.**

ORDER

AND NOW, this 28th day of June, 2019, upon consideration of Motion for Leave to File Defendants' Amended Answer to Plaintiffs' First Amended Complaint and Counterclaims (Document No. 43, filed June 11, 2019), Plaintiffs' Opposition to Defendants' Motion for Leave to File an Amended Answer and Counterclaims (ECF #43) (Document No. 45, filed June 19, 2019), Reply Memorandum in Support of Motion for Leave to File Defendants' Amended Answer to Plaintiffs' First Amended Complaint and Counterclaims (Document No. 48, filed June 26, 2019), Plaintiffs' Sur-reply to Defendants' Motion for Leave to Amend Answer and Counterclaim (Document No. 51, filed June 25, 2019), and plaintiffs' Exhibit H (Document No. 52, filed June 27, 2019), **IT IS ORDERED** that the Motion is **DENIED WITHOUT PREJUDICE** to defendants' right to file an amended answer asserting a claim of inequitable conduct that is compliant with this Order and Federal Rule of Civil Procedure 9(b) on or before July 10, 2019.

The decision of the Court is based on the following:

I. INTRODUCTION

In this patent infringement case, plaintiffs Becon Medical, Ltd., and Henry Stephenson Byrd, M.D., assert that defendants TalexMedical, LLC, and Scott P. Bartlett, M.D., infringed on

plaintiffs' U.S. Patent No. 8,167,942 ("942 Patent") and 8,852,277 ("277 Patent") (collectively, "the Patents"). *See* Am. Compl. ¶ 1. The Patents relate to a "non-surgical infant ear correction" device called EarWell that reshapes ear deformities in infants. *Id.* ¶ 2. Plaintiffs assert that defendants' infringed the Patents by "making, using, and selling" a non-surgical infant ear correction device called InfantEar. *See id.* ¶ 28.

On September 27, 2018, plaintiffs filed the Complaint (Document No. 1). On November 14, 2018, plaintiffs filed the Amended Complaint (Document No. 12). On December 11, 2018, defendants filed the Answer to the Amended Complaint, including counterclaims of non-infringement and invalidity (Document No. 15). Plaintiffs filed their Answer to defendants' counterclaims on December 31, 2018 (Document No. 18).

On May 23, 2019, defendants deposed plaintiff Dr. Byrd. During that deposition, Dr. Byrd testified about his knowledge of two articles—a 1998 article by Takatoshi Yotsuyanagi ("Yotsuyanagi Article") and a 2005 article by Anne Dancey ("Dancey Article")—as well as U.S. Patent No. 2,239,572 ("Jurovaty Patent"). Defs. Mem. Supp. Mot. Leave File Am. Answer ("Defs. Mot. Leave") 2. Defendants assert that these references were material to plaintiffs' Patents. *Id.*

On June 11, 2019, defendants filed Motion for Leave to File Defendants' Amended Answer to Plaintiffs' First Amended Complaint and Counterclaims, seeking to add a counterclaim of inequitable conduct on the ground that Dr. Byrd intended to deceive the U.S. Patent and Trademark Office ("USPTO") by failing to disclose these three allegedly material references in his applications for the '942 and '277 Patents. *See* Defs. Mot. Leave 2; Defs. Reply 4. Plaintiffs responded to the Motion on June 19, 2019 (Document No. 45). Defendants filed a reply via letter on June 21, 2019 (Document No. 48), and on June 25, 2019, plaintiffs filed a sur-

reply (Document No. 51). The Motion is now ripe for decision. For the reasons that follow, the Motion is denied without prejudice to defendants' right to file an amended answer that is compliant with Federal Rule of Civil Procedure 9(b) and this Order on or before July 10, 2019.

II. LEGAL STANDARDS

A. Rule 15(a)¹

Under Federal Rule of Civil Procedure 15(a)(2), “a party may amend its pleading only with the opposing party’s written consent or the court’s leave. The court should freely give leave when justice so requires.” Leave to amend should be “freely given” in the absence of “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment.” *Foman v. Davis*, 371 U.S. 178, 182 (1962).

B. Rule 9(b)

Federal Rule of Civil Procedure 9(b) requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1304 (Fed. Cir. 2011) (explaining “the strict pleading requirements of [Rule] 9(b) apply to counterclaims of inequitable conduct”). Under Rule 9(b), a party must plead “all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the ‘who, what, when, where, and how’ of the events at issue.” *See In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997)).

¹ If a party moves for leave to amend the pleadings after a deadline imposed by a Scheduling Order has passed, Federal Rule of Civil Procedure 16 demands that the “schedule may be modified only for good cause and with the judge’s consent.” Because the Scheduling Order in this case did not include a deadline for amending the pleadings, Rule 16 is not implicated.

III. DISCUSSION

Defendants argue Dr. Byrd intended to deceive the USPTO by deliberately failing to disclose three material references from his patent applications: the Yotsuyanagi Article, the Dancey Article, and the Jurovaty Patent. Defs. Mot. Leave 2; Defs. Reply 4. Plaintiffs argue that defendants' Motion does not satisfy Rule 15(a) because defendants did not unduly delay in filing the Motion, the amendment would unduly prejudice plaintiffs, and the inequitable conduct claim is futile. Pls. Opp. Defs. Mot. Leave 1, 8.

A. Undue Delay

Defendants maintain that because an inequitable conduct claim must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b), they waited until after Dr. Byrd's deposition to file the Motion to ensure that they could plead the specifics of their claim. Defs. Reply 3. For example, during the deposition, defendants confirmed that Dr. Byrd was personally aware of the alleged material references and the dates on which he became aware of those references. *Id.* Defendants then filed the Motion within three weeks of the deposition and within one week of receiving the deposition transcript. Defs. Mot. Leave 4. The Court thus concludes that defendants did not unduly delay in filing the Motion.

B. Undue Prejudice

Plaintiffs argue that they have already filed their opening claim construction brief, completed significant document discovery, and deposed defendants' Chief Technology Officer ("CTO"), former CEOs, and current CEO. Pls. Opp. Defs. Mot. Leave 8–9. However, plaintiffs do not explain how defendants' inequitable conduct claim would impact their claim construction briefs, discovery, or depositions. Because the inequitable conduct claim relates only to the conduct of plaintiff Dr. Byrd, the facts related to the claim are already in plaintiffs' possession—

there is no reason to depose defendants' CTO, former CEOs, or current CEO about the claim. Furthermore, discovery is still in its early stages, and no undue delay would result from granting the Motion.

C. Futility

The standard for assessing futility is the same as the legal sufficiency standard under Rule 12(b)(6). *See Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 243 (3d Cir. 2010). In other words, to determine whether an amendment is futile, a court should “tak[e] all pleaded allegations as true and view[] them in a light most favorable to the plaintiff.” *See Winer Family Trust v. Queen*, 503 F.3d 319, 331 (3d Cir. 2007). An inequitable conduct claim must be pled with particularity under Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326–27 (Fed. Cir. 2009). Plaintiffs argue that defendants' Motion should be denied because defendants have failed to comply with the pleading standards of Rule 9(b), or, in the alternative, because defendants cannot establish their inequitable conduct claim. *See* Pls. Opp. Defs. Mot. Leave 1. The Court addresses each of these arguments in turn.

First, plaintiffs argue that defendants' proposed Amended Answer fails to comply with the Rule 9(b) standard. *Id.* at 5–7. “To plead inequitable conduct, the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *See Sanders v. Mosaic Co.*, 418 F. App'x 914, 918 (Fed. Cir. 2011). “A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).” *Exergen*, 575 F.3d at 1326–27.

To plead inequitable conduct, a party must first plead sufficient facts “from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or

of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at 1328–29; *see also Eisai Co. v. Teva Pharm. USA, Inc.*, 629 F. Supp. 2d 416, 428–29 (D.N.J. 2009) (“Some courts have required that an inequitable conduct pleading state ‘specifically’ that the patent owner had an intent to deceive the PTO by literally including the words ‘intent to deceive.’”). Defendants’ proposed Amended Answer states that Dr. Byrd “willful[ly] and “deliberately omitted” the three references from his disclosures to the USPTO. Defs. Mot. Leave, Ex. A, Am. Answer ¶¶ 27, 29. Thus, defendants sufficiently allege that Dr. Byrd knew of the withheld material information and knew that he was not disclosing it to the USPTO, but not that Dr. Byrd did so with intent to deceive the USPTO. Without more, defendant has not adequately pled this element of inequitable conduct. *See Collaboration Props., Inc. v. Tandberg ASA*, No. 05-1940, 2007 WL 205065, at *3–4 (N.D. Cal. Jan. 25, 2007) (“Allegations that the patentee intentionally failed to cite a prior art reference or intended to disregard his or her duties to the PTO is not sufficient.”).

Second, the pleading must identify “which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the ‘what’ and ‘where’ of the material omissions.” *Exergen*, 575 F.3d at 1329; *see also Energy Absorption Sys., Inc. v. Roadway Safety Service, Inc.*, No. 93-2147, 1993 WL 389014, at *2 (N.D. Ill. Sept. 16, 1993) (explaining a party must plead “why or how [the] alleged omission was material”). Defendants’ proposed Amended Answer includes conclusory statements that the Yotsuyanagi and Dancey Articles and the Jurovaty Patent are “material” references and anticipatory of the Patents, but it does not identify “which claims” in the Patents “those references are relevant to,” nor “where in those references the material information is found.” *See* Defs. Mot. Leave, Ex. A, Am. Answer ¶¶ 27, 29; *see Exergen*, 575 F.3d at 1329.

Defendants’ argument that their Amended Invalidity Contentions (Document No. 29, filed March 19, 2019) explain the materiality of these references is insufficient—that document is not incorporated in the proposed Amended Answer. *See* Defs. Reply 5. Thus, defendants have failed to sufficiently plead the materiality element of inequitable conduct.

In the alternative, plaintiffs assert numerous arguments for why defendants will be unable to establish their inequitable conduct claim. *See* Pls. Opp. Defs. Mot. Leave 4–8. For example, plaintiffs maintain that defendants cannot show that the Dancey Article was material to the issuance of Dr. Byrd’s Patents. *Id.* at 8. They also state that the Dancey Article admits that the splint it discusses was not original and that four references, which Dr. Byrd cited in his ’942 and ’277 Patents, disclose the same or similar splints. *Id.* According to plaintiffs, because the USPTO issued the ’942 and ’277 Patents in spite of those four references, a cite to the Dancey Article would not have been material to the USPTO’s decision. *Id.*

“[F]actual disputes which would require an analysis of the evidence and go to the issue of whether [defendants] would ultimately prevail” are improper at this stage. *See Roquette Freres v. SPI Pharma, Inc.*, No. 06-540, 2009 WL 1444835, at *5 (D. Del. May 21, 2009). To determine whether the Court may grant defendants leave to amend, the question is only whether defendants “fail[ed] to allege any set of facts that could support a finding of inequitable conduct.” *See id.* The Court thus rejects plaintiffs’ arguments on the question whether defendants would ultimately prevail.

In sum, the Court concludes that defendants did not unduly delay in bringing the Motion, plaintiffs will not suffer undue prejudice by allowing defendants to amend their Answer, and plaintiffs’ arguments addressing whether defendants would ultimately prevail on an inequitable conduct claim are inappropriate at this stage of the proceedings. Defendants’ Motion is denied

only on the ground that defendants failed to adequately plead their inequitable conduct claim under Rule 9(b). This denial is without prejudice to defendants' right to file an amended answer that complies with this Order and Rule 9(b) on or before July 10, 2019.

IV. CONCLUSION

For the foregoing reasons, the Court denies the Motion without prejudice to defendants' right to file an amended answer that is compliant with this Order and Federal Rule of Civil Procedure 9(b) on or before July 10, 2019.

BY THE COURT:

/s/ Hon. Jan E. DuBois

DuBOIS, JAN E., J.